UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,936	10/20/2005	David Jackson	23133-09967	1891

758 7590 03/26/2009

FENWICK & WEST LLP
SILICON VALLEY CENTER
801 CALIFORNIA STREET
MOUNTAIN VIEW, CA 94041

EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
03/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,936	JACKSON ET AL.	
	Examiner	Art Unit	
	DAVID LUKTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) *4,10,13,14,26-30 and 40-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 34-37* is/are rejected.

7)☒ Claim(s) *6-9,11,12,15-25,31-33,38 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/08, 12/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-100 remain pending.

Applicant's previous election of Group I (claims 1-39, 52, 53, 66, 77, 88, 99) is again acknowledged.

Also acknowledged is applicants response to the "election of species" requirement. Claim 4 is withdrawn, since in the elected lipopeptide, the lipid moiety is not attached to a lysine that is positioned within the Th epitope. Claim 10 is withdrawn, since it does not correspond to the structure of the elected lipopeptide. Claim 13 is withdrawn, since in the elected peptide, the spacer does not consist only of two serines. Claim 14 is withdrawn, since in the elected peptide, the Th and CTL moieties are both bonded to the same lysine; a single lysine is not accurately described as being "nested within a synthetic amino acid sequence". Claims 26-29 are withdrawn, since in the elected lipopeptide, the CTL epitope is not from a eukaryotic organism. Claims 88 and 99, are withdrawn, at least temporarily. Claims 40-51, 54-65, 67-76, 78-87, 89-98, 100 are also withdrawn, as preemptively noted by applicants.

Claims 1-3, 5-9, 11, 12, 15-25, 31-39 are examined in this Office action; claims 4, 10, 13, 14, 26-30, 40-100 are withdrawn.

Claims 1-3, 5, 34-37 are now rejected. Claims 6-9, 11, 12, 15-25, 31-33, 38, 39 are objected to because of their dependence on a rejected claim (although may be rejected in a subsequent Office action).

Claims 34-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 42 of copending application Serial No. 10/525301. Although the conflicting claims are not identical, they are not patentably distinct from each other. According to one interpretation, the claims of both applications permit the epitope to be that of a T helper; neither a CTL epitope, nor a B cell epitope is required. This interpretation is justified because in formula VI (claim 34), the "epitope" can be **either** a T helper **or** a CTL, notwithstanding the directive in part (i) of claim 34.

[This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each

claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3, 5 are rejected under 35 U.S.C. §103 as being unpatentable over Nardin (*Vaccine* **16**, 590-600, 1998).

Nardin discloses (figure 1) vaccines based on branched templates. Figure 1B shows the "big picture" scheme, and figure 1E shows the molecular structures involved. Note that both of the structures in figure 1E meet the requirement (instant claim 1) for an "internal" lysine to which is attached a lipid moiety. Note also that the T* epitope contains both CD4+ and CD8+ epitopes (see, e.g., page 599, col 1, first paragraph). Note also that instant claim 1 does not exclude the presence of B cell epitopes.

The presence of the following phrase in claim 1 is acknowledged: "wherein said amino acid sequences are different". However, the CD4+ and CD8+ epitopes of the Nardin disclosure will not coincide exactly, even if it is true that they are both present on a given peptide "X", such that "X" is identical to itself.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Tam (USP 5,580,563).

Tam discloses (figure 1) a vaccine in which antigens are present, and a lipophilic group is bonded to an internal lysine. Also disclosed (e.g., col 5, line 55+) is that Th and CTL epitopes can both be present.

Thus, the claim is rendered obvious.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Tam (USP 5,580,563) in view of Sauzet (*Vaccine* **13**(14), 1263-1384, 1995).

The teachings of Tam are noted above. Tam does not suggest the use of a single peptide that contains both CD4 and CD8 epitopes. However, this is disclosed in Sauzet. It would have been obvious to attach the peptides of Sauzet to the MAP system of Tam for the benefits disclosed in Tam.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654